

## Food and Drug Administration, HHS

§ 558.58

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Erythromycin 92.5 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.  Feed for 7 to 14 d; withdraw 24 h before slaughter.	
	Erythromycin 185 .....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d, do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Hygromycin B 8 to 12	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infestation of large round worms ( <i>Heterakis gallinae</i> ) and capillary worms ( <i>Capillaria obsignata</i> ).	Feed according to subtable in item (i).	
	Penicillin 2.4 to 50 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	As procaine penicillin.  .....do.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.  .....do.	
(v) 227 (0.025%) .....	.....	Laying chickens; treatment of coccidiosis.	For severe outbreaks of coccidiosis; administer for 2 weeks.	

(3) *Pheasants*. It is used as follows:

(i) *Amount*. 0.0175 percent (159 grams per ton).

(ii) *Indications for use*. For the prevention of coccidiosis in growing pheasants caused by *Eimeria colchici*, *E. duodenalis*, and *E. phasiani*.

(iii) *Limitations*. Feed continuously as sole ration. Use as sole source of amprolium. Fertility, hatchability, and other reproductive data are not available on amprolium in breeding pheas-

ants. Do not use in feeds containing bentonite.

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

#### § 558.58 Amprolium and ethopabate.

(a) *Approvals*. Type A medicated articles: (1) 25 percent amprolium and 0.8

§ 558.58

21 CFR Ch. I (4–1–05 Edition)

percent ethopabate; 25 percent amprolium and 8 percent ethopabate; 5 percent amprolium and 0.16 percent ethopabate; 5 percent amprolium and 1.6 percent ethopabate; to 000006.

(2) 0.15 percent amprolium and 0.004 percent ethopabate and 0.05 gram per pound bacitracin (as bacitracin meth-

ylene disalicylate) to 047019 in § 510.600(c) of this chapter.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See §§ 556.50 and 556.260 of this chapter.

(d) *Conditions of use.* (1) It is used for chickens as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	.....	Broiler chickens as an aid in the prevention of coccidiosis.	Not for laying hens; as sole source of amprolium.	
(ii) Amprolium 113.5 (0.0125%) and ethopabate 3.6 (0.0004%).	Bambermycins 2 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone by No. 046573, bambermycins by No. 057926; withdraw 5 d before slaughter.	
	Lincomycin 2 to 4 ....	Broiler chickens; for increase in rate of weight gain; improved feed efficiency; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.	
	Lincomycin 2 to 4 plus roxarsone 45.4 (0.005%).	Broiler chickens; for increase in rate of weight gain; improved feed efficiency and pigmentation; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic.	
	Roxarsone 45.4 (0.005 pct).	Broiler chickens; to aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as sole ration from time chickens are placed on litter until the past the time when coccidiosis is ordinarily a hazard; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combinations as provided by No. 050604.	
(iii) Amprolium 113.5 (0.0125%) and ethopabate 36.3 (0.004%).	.....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur.	Not for chickens over 16 weeks of age.	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improve pigmentation.	Not for laying hens; withdraw 5 d before slaughter; as sole source of organic arsenic; as erythromycin thiocyanate.	061133

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 4 to 50 ....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis; as bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; combination as provided by No. 050604 in § 510.600(c) of this chapter.	046573
	.....	2. Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; improved feed efficiency.	Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis; bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until market weight; combination as provided by No. 046573..	
	Bacitracin 5 to 35 plus roxarsone 34 (0.00375%).	Broiler chickens; for increased rate of weight gain and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combination as provided by No. 050604 in § 510.600(c) of this chapter.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 20 to 35 plus roxarsone 34 (0.00375%).	Broiler chickens; for increased rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combination as provided by No. 050604 in § 510.600(c) of this chapter.	
	Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017% to 0.005%).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; improved feed efficiency.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter; bacitracin zinc as provided by No. 046573 roxarsone as provided by No. 046573 combination as provided by No. 046573.	046573
	Bacitracin 10 plus roxarsone 30 to 45.4 (0.0033% to 0.005%).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; improved feed efficiency and improved pigmentation.	.....do .....	063238
	Bambermycins 1 to 3.	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain, and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium; amprolium, ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, bambermycins as provided by No. 057926 in § 510.600(c) of this chapter.	
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain; improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 050604 in § 510.600(c) of this chapter, roxarsone by No. 046573 bambermycins by No. 057926. Withdraw 5 days before slaughter.	
	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	Not for laying hens; withdraw 24 hours before slaughter; erythromycin thiocyanate.	

## Food and Drug Administration, HHS

§ 558.58

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iv) Amprolium 113.5 to 227 (0.0125% to 0.025%) and ethopabate 3.6 (0.0004%).	Virginiamycin, 15 .....	Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to <i>Eimeria acervulina</i> , <i>E. brunetti</i> , and <i>E. maxima</i> is likely to occur, for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration, do not feed to laying hens, not for chickens over 16 weeks of age, as sole source of amprolium, amprolium and ethopabate as provided by 050604 in § 510.600(c), virginiamycin as provided by 066104.	000069
	Virginiamycin, 5 to 15.	Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to <i>Eimeria acervulina</i> , <i>E. brunetti</i> , and <i>E. maxima</i> is likely to occur, for increased rate of weight gain.	.....do.	
	.....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying hens.	
	Arsanilic acid 90 (0.01%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation. 2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic; not for laying hens.	
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50 ....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate; not for laying hens.	
	Bacitracin 100 to 200.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	.....do.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	As zinc bacitracin, not for laying hens.	
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As bacitracin methylene disalicylate; not for laying hens; as sole source of organic arsenic; withdraw 5 d before slaughter.	
	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	
	Erythromycin 92.5 ...	1. For broiler chickens and for replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; not for laying hens.  Feed for 7 to 14 d; withdraw 24 h before slaughter; not for laying hens.	
	Erythromycin 185 ....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Penicillin 2.4 to 50 ...	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Not for laying hens; as procaine penicillin.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	

(2) [Reserved]

[41 FR 10990, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.58, see the List of CFR Sections Affected, which appears in the

## Food and Drug Administration, HHS

## § 558.62

Finding Aids section of the printed volume and on GPO Access.

### § 558.59 Apramycin.

(a) *Approvals.* Type A articles to sponsors identified in § 510.600(c) of this chapter as follows:

(1) 000986 for 75 grams apramycin (as apramycin sulfate) per pound for use as in paragraph (d)(1) of this section.

(2) [Reserved]

(b) [Reserved]

(c) *Related tolerances.* See § 556.52 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount.* 150 grams per ton.

(ii) *Indications for use.* For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of *Escherichia coli*.

(iii) *Limitations.* Use for 14 days. Withdraw 28 days before slaughter.

(2) [Reserved]

[51 FR 9190, Mar. 18, 1986]

### § 558.60 Arsanilate sodium.

(a) *Approvals.* Type A medicated articles: 20, 50, or 100 percent to 015565 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.60 of this chapter.

(c) *Conditions of use.* (1) It is used for chickens and turkeys as follows:

(i) *Grams per ton.* 90 (0.01 percent).

(ii) *Indications for use.* For growth promotion and feed efficiency; improving pigmentation.

(iii) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) Arsanilate sodium may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Zoalene in accordance with § 558.680.

[41 FR 10992, Mar. 15, 1976, as amended at 51 FR 7395, Mar. 3, 1986; 51 FR 33897, Sept. 24, 1986]

### § 558.62 Arsanilic acid.

(a) *Approvals.* Type A medicated articles to sponsors in § 510.600(c) of this chapter as follows:

(1) To 015565: 20, 50, and 100 percent for use as in the table in paragraph (c)(1), entry (ii), item 1; entry (ii), item 2; entry (iv); entry (vi); and entry (vii) of this section.

(2) To 015565: 20 percent for use as in paragraph (c)(1), entry (i); entry (ii), item 3 of this section.

(3) To 061133: 90 grams per pound arsanilic acid and 4.6 grams per pound erythromycin equivalents as erythromycin thiocyanate for use as in paragraph (c)(1), entry (iii); 90 grams per pound arsanilic acid and 9.25 grams per pound erythromycin equivalents as erythromycin thiocyanate for use as in paragraph (c)(1), entry (v).

(b) *Related tolerances.* See § 556.60 of this chapter.

(c) *Conditions of use.* (1) It is used as follows:

Arsanilic acid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 45 to 90 .....	.....	1. Growing chickens: For growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 days before slaughter; as sole source of organic arsenic.	015565
	.....	2. Growing turkeys: For growth promotion and feed efficiency; improving pigmentation.	.....do .....	015565
	.....	3. Growing swine: For increased rate of weight gain and improved feed efficiency.	.....do .....	015565
(ii) 90 .....	.....	Swine: As an aid in control of swine dysentery (hemorrhagic enteritis, bloody dysentery).	.....do .....	015565
(iii) .....	Erythromycin 4.6 .....	Chickens: growth promotion and feed efficiency; improving pigmentation..	As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic..	012487
(iv) .....	Erythromycin 4.6 to 18.5.	Chickens: growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic.	15565